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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,940	03/01/2002	Scan T. O'Mara	920070.417	6662
30465 7590 08/31/2007 SEED INTELLECTUAL PROPERTY LAW GROUP LLC SUITE 5400 701 FIFTH AVENUE SEATTLE, WA 98104-7092			EXAMINER DIXON, ANNETTE FREDRICKA	
			ART UNIT 3771	PAPER NUMBER
			MAIL DATE 08/31/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/086,940

Applicant(s)

O'MARA, SEAN T.

Examiner

Annette F. Dixon

Art Unit

3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 66-71, 73-78 and 80-118 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 66-71, 73-78 and 80-118 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 August 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. This Office Action is in response to the request for continued examination filed on June 28, 2007. Examiner acknowledges claims 66-71, 73-78, and 80-118 are pending in this application, with claims 80-118 having been newly added.

#### ***Continued Examination Under 37 CFR 1.114***

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 28, 2007 has been entered.

#### ***Drawings***

3. New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the drawings submitted August 28, 2007 are not compliant with the standards for drawings as set forth in CFR §1.84. Specifically, the reference characters are not plain and legible (CFR §1.84 (p) (1)), and the photos of Figures 8-11 and 13-16 are not of sufficient quality so that the details in the photographs are reproducible in the printed patent (CFR §1.84 (b) (1)). Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to

the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 66, 67, 71, 73, 74, 78, 90-92, 94, 95, and 112-118 are rejected under 35 U.S.C. 102(b) as being anticipated by Parker (5,873,362).

As to Claims 66, 73, 90-92, Parker discloses a method comprising: inserting an intubation-tube placement device (73) secured to an intubation tube (10), into a patient's oral cavity; detecting the cartilaginous rings of the trachea via at least one tactile-accentuator (54) device coupled to the intubation-tube placement device (via the cooperative interaction of elements 73 and 10); forcing the intubation-tube placement device through the patient's vocal cords (88, using the distal end 18 of the intubation tube 10) and axially sliding the intubation tube (10) along the intubation-tube placement device (73) such that the intubation tube (10) follows the intubation-tube placement device through the patient's vocal cords. (Figures 4A and 4B). As seen in Figure 4B, the tactile-accentuator (54) guides the intubation tube (10) along the cartilaginous rings (90). In regards to claim 73, the exploratory portion (74) is shaped to prevent the intubation-tube placement device from perforating an internal body structure during

insertion into the patient's oral cavity. In regards to claims 90-92, Parker discloses the placement device (73) may be removed from the intubation tube (10). (Column 5, Lines 15-20).

As to Claims 67, 74, Parker discloses the operation of the intubation tube placement device may additionally encompass the use of a light source (100). (Column 5, Lines 20-24).

As to Claims 71, 78, Parker discloses the forcing of the intubation-tube placement device through the patient's vocal cords, comprises: applying axial pressure along the intubation-tube placement device such that the intubation-tube placement device moves into the patient's trachea. (Column 5, Lines 2-20).

As to Claim 94, Parker discloses detecting the cartilaginous rings of the trachea via at least one tactile-accentuator (54) device coupled to the intubation-tube placement device (via the cooperative interaction of elements 73 and 10). (Figures 4A and 4B). As seen in Figure 4B, the tactile-accentuator (54) guides the intubation tube (10) along the cartilaginous rings (90).

As to Claim 95, Parker discloses a plurality of ventilation holes (120) along the wall in the portion of the endotracheal tube (10) that follows the endotracheal placement device. (Column 5, Lines 47-57).

As to Claim 112, Parker discloses a intubation tube (10), comprising: a first end (16) having a first opening; and a second end (18) configured to pass through a set of vocal cords (88); a plurality of openings (12) on a portion of the wall of the intubation tube (10) adjacent to the second end (18) of the intubation tube. (Figure 1, 4A, and 4B).

As to Claim 113-118, Parker discloses a tip (58) of the second end (18) of the intubation tube is rounded in shape and tapered.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 68-70, 75-77, and 93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parker (5,873,362) in view of Flam (5,607,386).

As to Claims 68, 75, and 93, Parker discloses the recited method but does not expressly disclose the suctioning of materials. However, at the time the invention was made, the use of suctioning materials formed within the intubation-tube placement device was known. Specifically, Flam, in a method of inserting an intubation-tube placement device, teaches suctioning materials from a vicinity of the patient's vocal cords via a suction tube formed by the intubation-tube placement device (col.7, lines 50-59) for the purpose of clearing mucous and debris from a patient's respiratory tract. Flam also discloses the use of the suction tube for insufflating a patient for providing breathable gas to a patient during the intubation process. Therefore, it would have been obvious to modify the intubation-tube placement device of Parker to provide a suction tube for suctioning materials from a vicinity of a patient's vocal cords because it would have provided a means for clearing mucous and debris from a patient's respiratory tract

as well as provided a means for delivering breathable gas to a patient during the intubation process as taught by Flam.

As to Claims 69 and 76, Parker as modified by Flam teaches the intubation-tube placement device forming a hollow tube (suction lumen extends entire length of device as disclosed at col.7, lines 50-59 of Flam).

As to Claims 70 and 77, Flam teaches the suction tube formed by the intubation tube placement device comprises: the intubation-tube placement device forming a hollow tube (i.e. note insufflation and suction lumen that extends entire length of device); an anti-perforation device having a trailing portion (e.g. adjacent handle #13) and an exploratory portion; a channel (col.7, lines 50-59) between the trailing portion and the exploratory portion of said anti-perforation device, and the trailing portion coupled to said intubation-tube placement device such that the channel substantially aligns with hollow tube.

8. Claims 80-88, 96-99, 109-111 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parker ('362) in view of Flam ('386), and further in view of Slanetz, Jr. ('091).

As to Claims 80, 88, 96, 98, 109, 110, Parker discloses an intubating apparatus having a intubation placement device (10) and a retention device (73), yet does not expressly disclose the particulars of the intubation placement device nor the anti-perforation device. However, at the time the invention was made the structural particulars of the intubation placement device and the anti-perforation device were

known. Specifically, Flam ('386) teaches an apparatus comprising: an intubation tube placement device (10); and an anti-perforation device (21,22) coupled to said intubation tube placement device for assisting in the placement of the intubating member into the patient's trachea. However, the system of Parker as modified by Flam does not expressly disclose the anti-perforation device having an exploratory portion shaped to prevent the anti-perforation device from perforating an internal body structure during insertion. Slanetz, Jr. teaches an anti-perforation device (12) having an exploratory portion (25) shaped to prevent the anti-perforation device from perforating an internal body structure for the purpose of preventing the rupture (i.e. perforation) of a duct by signaling a control unit of an area of greatest pressure being exerted on the exploratory portion (col.2, lines 43-47 and lines 62-65). Therefore, it would have been obvious to modify system of Parker/ Flam to include an exploratory portion of the anti-perforation device shaped to prevent perforation of an internal body structure during insertion, as taught by Slanetz, Jr. to provided a means for preventing the rupture of a duct by signaling a control unit of an area of greatest pressure being exerted on the exploratory portion.

As to Claims 81, 82, 97, 111, Flam (figs.2,3,5,7) teaches an intubation tube (24) secured to the intubation tube placement device (12), the intubation tube placement device being internal to the intubation tube and a retaining device comprising a rubber stopper (23) having a hole through which the intubation tube placement device (12) extends, the retaining device being in contact with said intubation tube.



As to Claim 83, 99, Flam (col.7, lines 50-59) discloses said intubation tube placement device forms a hollow tube (i.e. note insufflation and suction lumen that extends entire length of device); said anti-perforation device having a trailing portion (e.g. adjacent handle #13) and an exploratory portion (e.g. adjacent tip of device #21) and a channel (col.7, lines 50-59) between the trailing portion and the exploratory portion of said anti-perforation device; and the trailing portion coupled to said intubation tube placement device such that the channel aligns with the hollow tube.

As to Claim 84, Parker discloses the operation of the intubation tube placement device may additionally encompass the use of a light source (100). (Column 5, Lines 20-24). In addition, Flam discloses a fiber optic device includes a light source (col.7, line 49).

As to Claims 85, 86, 87, 100, Flam discloses the intubation placement device (12) is a medical device made of a malleable material. (Column 4, Lines 40-65).

As to Claim 89, 101, 102, 104, 105, Parker discloses at least one tactile-accentuator (54) device coupled to the intubation-tube placement device for detecting the cartilaginous rings of the trachea (via the cooperative interaction of elements 73 and 10). (Figures 4A and 4B). As seen in Figure 4B, the tactile-accentuator (54) guides the intubation tube (10) along the cartilaginous rings (90).

As to Claim 103, 106, 107, Parker discloses a plurality of ventilation holes (120) along the wall in the portion of the endotracheal tube (10) that follows the endotracheal placement device. (Column 5, Lines 47-57).

As to Claim 108, Parker discloses an inflatable cuff (24) and a plurality of ventilation holes (120) along the wall in the portion of the endotracheal tube (10) that follows the endotracheal placement device. (Column 5, Lines 47-57).

### ***Response to Arguments***

9. Applicant's arguments with respect to claims 66-71, and 73-78 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3771

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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Art Unit 3771



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8/29/07